

### **Remarks**

Reconsideration and withdrawal of the objections to and rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 1, 19, 25-26, 61, 63, and 66 are amended, claims 20, 24, 41-43, and 47 are canceled, and claims 68-69 are added. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the claims prior to amendment, which claims are present in a continuation of the above-identified application. Claims 1-3, 8-11, 19, 21, 23, 26-37, 46, 48-54, and 58-69 are now pending.

The Examiner objected to claims 63 and 66 under 37 C.F.R. § 1.75(c) as being of improper dependent form for not further limiting the subject matter of a previous claim. However, claim 63 is directed to a composition comprising the two rAAVs of claim 60, and claim 66 is directed to a composition comprising the two rAAVs of claim 61. Therefore, claim 63 and 66 are of a different scope than claims 60 and 61, respectively. Nevertheless, to advance the application, claims 63 and 66 are amended.

The Examiner rejected claims 19-20 and 47 under 35 U.S.C. § 102(e) as being anticipated by Engelhardt et al. (U.S. Patent No. 6,436,392). The Examiner also rejected claims 1, 9, 19-20, 46-47, and 58-59 under 35 U.S.C. § 102(b) as being anticipated by Rendahl et al. (Nature Biotechnology, 16:757 (1998)). These rejections, as they may be maintained with respect to the pending claims, are respectfully traversed.

The cancellation of claims 20 and 47 moot the 35 U.S.C. § 102(e) and § 102(b) rejections of those claims.

It is disclosed in the '392 patent that rAAV vectors, each containing a promoter and an open reading frame between ITRs, may become linked after infection of the host cell with the vectors and synthesis of double-stranded viral DNA (column 4, lines 41-56 and column 5, lines 26-38). Other vectors disclosed in the '392 patent include rAAV vectors that contain an open reading frame flanked by a splice site, i.e., one rAAV vector contains a splice acceptor site and another rAAV vector contains a splice donor site, which vectors together encode a functional gene product (column 4, lines 57-column 5, line 25). It is disclosed that transcription of a

molecule formed by linking the two rAAVs in a cell results in a spliced RNA molecule which encodes a functional peptide (column 49, lines 14-22).

In neither embodiment disclosed in Engelhardt et al. does the rAAV vector with a non-ITR promoter include a non-ITR promoter positioned so that it is capable of regulating transcriptional expression of a functional gene product encoded by another rAAV vector, where the vector with the non-ITR promoter does not encode a protein. Thus, Engelhardt et al. do not teach Applicant's invention.

The Rendahl et al. article discloses two rAAV vectors, one having a tetracycline sensitive operator sequence linked to a minimal CMV promoter which controls expression of a murine erythropoietin (epo) transgene (rAAV-(tetO)7-minCMV-mEPO), and the other having a CMV promoter controlling expression of a tetracycline responsive transactivator, tTA (abstract and Figure 1, rAAV-CMV-tTA), i.e., it is an operon like system. Each of the vectors in Rendahl et al. encodes a protein. Accordingly, Applicant's invention is not disclosed in Rendahl et al.

Therefore, withdrawal of the § 102 rejections is respectfully requested.

The Examiner also rejected claim 47 under the judicially created doctrine of obviousness-type double patenting over claims 8-15 of U.S. Patent No. 6,436,392. The cancellation of claim 47 obviates the obviousness-type double patenting rejection of that claim.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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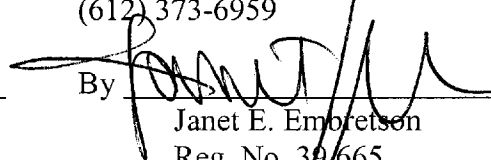
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This paper or fee is being filed on the date indicated above using the USPTO's electronic filing system EFS-Web, and is addressed to: The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**CANDIS BUENDING**

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